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Date: July 23, 2008 Nicole Readence
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Applicant(s): Kusama, *et al.*

Serial No: 10/826,119

Filing Date: April 16, 2004

Examiner: Suryaprabha Chunduru

Art Unit: 1637

Title: OLIGONEUCLEOTIDE SEQUENCES THAT IDENTIFY SPECIES OF ANIMAL

**Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

REPLY BRIEF

Dear Sir:

Appellants' representative submits this brief in connection with an appeal of the above-identified patent application and in response to the Examiner's Answer dated May 23, 2008. In the event any additional fees may be due and/or are not covered by the credit card, the Commissioner is authorized to charge such fees to Deposit Account No. 50-1063.

I. Status of Claims (37 C.F.R. §41.37(c)(1)(iii))

Claims 1-23, 26-34, and 36-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected Group. Claims 24-25 and 35 stand rejected by the Examiner. The rejection of claims 24-25 and 35 is being appealed.

II. Grounds of Rejection to be Reviewed (37 C.F.R. §41.37(c)(1)(vi))

- A.** Whether claims 24-25 and 35 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Saulle et al (*Journal of Animal Science*, vol. 77, p. 3389, 1999) in view of Lowe et al (*Nucleic Acid Research*, vol. 18, p. 1757, 1990)?

III. **Argument (37 C.F.R. §41.37(c)(1)(vii))**

A. **There is no evidence that the program of Lowe et al will produce the claimed primer pairs.**

The Examiner states “[t]he Appellants did not dispute that the references do not teach and suggest each of the primer sequences.” Examiner’s Answer, page 5, last paragraph (underline added). We believe that the underlined is a grammatical error and that the sentence is supposed to read with the underlined portion omitted. We do not concede that the references teach the claimed primer sequences; our position has always been that whether or not the program of Lowe et al may conceivably produce the claimed sequences is not relevant to patentability, since selecting the specific sequences claimed is not obvious to achieve discriminatory function.

Further, a close reading of Lowe et al suggests that the program will not produce the claimed primers. On page 1758, column 1, first paragraph of Lowe et al, Lowe et al teaches that “[a]ll primers should contain a GC-type sequence pair (i.e., either a CC, GG, GC, or CG) at their 3’ end.” The function of the algorithm is further described as “choosing sense primers with the GC-type sequence pair at their 3’ ends.” Lowe et al., page 1759, column 2, first full paragraph.

That is, Lowe et al directly teaches an algorithm that will only suggest primers having the GC-type sequence pair at the 3’ end. The 3’ end of claimed SEQ ID NO: 3 through 6 are as follows: CA, GT, CA and GT. None of the claimed primer sequences have a GC-type sequence pair at their 3’ end. Therefore, the program of Lowe et al will not produce any of the claim primers regardless of any sequence entered into the program.

B. The discriminating properties between ruminant and non-ruminant primers is relevant to the present context since such discriminating properties demonstrate that the combination of Saulle et al and Lowe et al asserted by the Examiner is non-obvious.

On page 10 of the Examiner's Answer, the Examiner states that "the arguments based on discriminating primers to detect ruminant vs. non-ruminant DNA sequences is irrelevant to the present context." In order for a § 103 rejection to be proper, "an explanation why one of ordinary skill in the art . . . would have been motivated to make" to make the proposed combination is required. MPEP § 706.02(j)(D).

The program of Lowe et al requires a user to enter "a choice of which region of the original sequence to search for PCR primers." Lowe et al, page 1758, column 1, penultimate paragraph. That is, a user must have some motivation to select primers to be complementary to a particular region of an entered sequence. The Examiner asserts that "[i]t would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the known nucleic acid sequence as taught by Saulle et al. with a step of generate primers and designing primers as taught by Lowe et al." Examiner's Answer, page 3, last paragraph. However, the Examiner fails to mention or discuss the required step of selecting "a choice of which region of the original sequence to search for PCR Primers," which is required for the operation of the program of Lowe et al.

Based on the numbering reported in Saulle et al, SEQ ID NO: 3 and 5 are roughly aligned with bases 127-149 and SEQ ID NO: 4 and 6 are roughly aligned with bases 210-231. Figure 1 of Saulle et al depicts the gene coding for ATPase8 in non-underlined capital letter. The regions for alignment of both claimed primer pairs are well within the coding region of the gene, where the coding region is from bases 117-317. Those having ordinary skill in the art are normally motivated to select primers that flank the coding region for a gene, since under such conditions the entire gene is amplified by PCR for purposes of

sequencing, cloning, or sub-cloning. The Examiner has stated no reason why an individual would operate the Saulle et al program in a manner as to select primers well within the coding region of the ATPase8 gene as to generate the claimed primers.

The Inventors have chosen the primers in a manner to enhance the species discriminating properties of the claimed primers. There is no reason for one ordinarily skilled in the art to select the specific primers claimed nor to operate the program Lowe et in a manner such that the claimed primers are generated.

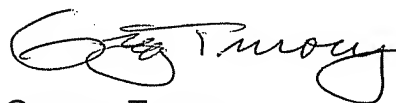
C. The Application provides ample support and examples of the discriminatory properties of the claimed primers.

On page 10 of the Examiner's answer, the Examiner states that "Appellants have not shown any evidence to show that the primers as claimed discriminate between homologous DNA sequences." The Application shows ample examples of the discrimination properties of the claimed primers. The homology of ATPase8 genes among various species discussed in the Application is shown in Figures 1-3. Figure 6 shows the discrimination functionality of the claimed ruminant-specific primers. It can be seen that the claimed primers (e.g., SEQ ID NO: 3 & 4) can discriminate between cattle, sheep and goat (all ruminants) and non-ruminant, mammal species such as whale and pig, as well as other species. The existence of other primes that can amplify a discrete PCR product for all the preceding species (e.g., SEQ ID NO: 1 & 2 and Figure 5) is evidence of homology between all species discussed in the Application and that the discrimination function is an engineered functionality.

D. Conclusion

For at least the above reasons, the claims currently under consideration are believed to be patentable over the cited art. Therefore, it is respectfully requested that the rejections of claims 24, 25, and 35 under 35 U.S.C. § 103 be withdrawn.

Respectfully submitted,
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